



**9110-04-P**

**DEPARTMENT OF HOMELAND SECURITY**

**Coast Guard**

**46 CFR Part 10**

**[Docket No. USCG-2018-0041]**

**COMDTINST M16721.48 Merchant Mariner Medical Manual**

**AGENCY:** Coast Guard, DHS.

**ACTION:** Notification of availability.

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**SUMMARY:** The Coast Guard announces the availability of the Merchant Mariner Medical Manual, Commandant Instruction Manual (COMDTINST M16721.48). The guidance in this Manual should assist medical practitioners, the maritime industry, individual mariners, and Coast Guard personnel in evaluating a mariner applicant's physical and medical status to meet the requirements of the merchant mariner medical certificate. This Manual incorporates and consolidates prior guidance on the medical evaluation of merchant mariners contained in several Coast Guard documents. The Manual includes guidance on the medical certificate and related processes, including procedures for application, issuance, and cancellation of the medical certificate.

**DATES:** The Merchant Mariner Medical Manual, COMDTINST M16721.4, is effective on [INSERT DATE OF PUBLICATION IN THE FEDERAL REGISTER].

**FOR FURTHER INFORMATION CONTACT:** For information about this document or to suggest changes, call or e-mail Adrienne Buggs, M.D., United States Coast Guard, Office of Merchant Mariner Credentialing; telephone: 202-372-2357, e-mail: MMCPolicy@uscg.mil.

## **SUPPLEMENTARY INFORMATION:**

### Viewing Documents

The Merchant Mariner Medical Manual, COMDTINST M16721.4, is available on the Internet at: <https://www.dcms.uscg.mil/Our-Organization/Assistant-Commandant-for-C4IT-CG-6/The-Office-of-Information-Management-CG-61/About-CG-Directives-System/> and on CGPortal at:

<https://cgportal2.uscg.mil/library/directives/SitePages/Home.aspx>. A link to the document will also be located on the National Maritime Center (NMC) site:

<https://www.dco.uscg.mil/Our-Organization/Assistant-Commandant-for-Prevention-Policy-CG-5P/National-Maritime-Center/>.

### Background and Discussion of the Merchant Mariner Medical Manual

Coast Guard regulations contained in 46 CFR part 10, subpart C, provide the medical and physical standards that merchant mariner applicants must meet prior to being issued a merchant mariner medical certificate. The Merchant Mariner Medical Manual provides guidance to the regulated community on how to comply with the regulations pertaining to medical and physical qualifications for merchant mariners.

Previously, the Coast Guard provided guidance on the medical and physical

requirements for merchant mariners in the Medical and Physical Evaluation Guidelines for Merchant Mariner Credentials, Navigation and Inspection Circular (NVIC) 04-08, Commandant Publication (COMDTPUB) 16700.4; in the Guidance on the Issuance of Medical Certificates (NVIC 01-14); and in Part A of the Marine Safety Manual, Volume III, Marine Industry Personnel, COMDTINST M16000.8 (Series) [MSM]. The Merchant Mariner Medical Manual revises, updates and combines the medical evaluation guidance previously published in NVIC 04-08, Part A of the MSM, Volume III, and NVIC 01-14. The Coast Guard developed the draft Manual in consultation with experienced maritime community medical practitioners and industry stakeholders serving on the Merchant Mariner Medical Advisory Committee (MEDMAC) and the Merchant Marine Personnel Advisory Committee (MERPAC). The Manual reflects a synthesis of their recommendations and the medical requirements of title 46 Code of Federal Regulations (CFR) part 10, subpart C.

Members of the public participated in the development of medical policy by providing comment and serving on working groups at the public meetings of MEDMAC and MERPAC. Additionally, the public had the opportunity to comment on drafts of policies contained in this Manual, and its predecessor, NVIC 04-08. See requests for comment on proposed policies regarding: Diabetes, cardiomyopathy, and sleep disorders (80 FR 8586, Feb. 18, 2015); Medications (80 FR 4582, Jan. 28, 2015); Seizures (78 FR 17917, Mar. 25, 2013); and Implantable cardioverter defibrillators (77 FR 55174, Sep. 7, 2012). The Coast Guard considered these public comments when developing this Manual.

### Public Comments on the Draft Merchant Mariner Medical Manual:

The Coast Guard published a draft of the Merchant Mariner Medical Manual in the Federal Register and sought input from the public on the draft (83 FR 56272, Nov. 13, 2018). The current version of the Manual includes revisions made to address comments received in response to the Federal Register notification. While the Coast Guard is not required to seek or respond to public comments prior to publication of a policy document, we chose to do so in this case because of the perceived complexity of the Merchant Mariner Medical Manual, and because doing so provides us the opportunity to 1) create a guidance document that is more viable and responsive to the needs of the impacted community; and 2) to identify and clarify remaining areas of confusion and concern amongst the regulated community.

The Coast Guard's notification sought general comments on the draft Medical Manual, with emphasis on suggestions to improve readability, clarity, and ease of use; and comments on whether the draft Manual's proposed medical certificate cancellation policy adequately addresses safety concerns in situations where the Coast Guard receives information indicating that a medical certificate holder has developed a medical condition that poses a significant risk of sudden incapacitation, or is taking a medication that poses a significant risk of impairment. The Coast Guard received 37 comment letters in response.

### General Comments:

Ten comment letters provided a general opinion of the draft Manual, with the majority expressing an overall positive opinion. These commenters found the guidance in the Manual to be thorough, straightforward and easy to use, and they found that it

answered many questions that had arisen with previous medical policy documents. The favorable commenters appreciated that the document provides medical evaluators, mariners and medical providers with needed and relevant information that will reduce the need for “back and forth” between the mariner and the National Maritime Center. They also found it helpful that the Manual outlines the Coast Guard’s general concerns with particular medical conditions and discusses the general factors that the Coast Guard will use to evaluate the medical condition and make a fitness determination. Comments provided by the National Transportation Safety Board (NTSB) found that the draft Medical Manual aptly streamlines the medical certification guidance and provides a level of detail that should assist medical personnel during the mariner medical certification exams. The NTSB comment letter also provided the following observations:

The combination of the Coast Guard’s increased oversight of medical certification and development of medical guidance appears to be highly effective at addressing safety concerns regarding medical conditions that pose a significant risk of sudden incapacitation. Since 2009, the NTSB has not found any medical conditions to have contributed to the probable cause of a marine accident. However, the NTSB continues to find effects from impairing substances (alcohol and over-the-counter, prescription, or illicit drugs) to have contributed to the probable cause across all modes of transportation.

One comment letter expressed a generally negative opinion of the draft Medical Manual. This commenter expressed concerns that the guidance in the Medical Manual would sacrifice maritime safety unless the Coast Guard provided further clarification and

a plan for implementation. Additionally, the commenter opined that the guidance does not adequately ensure that medical conditions are sufficiently controlled for those mariners at higher risk, because the Medical Manual does not establish clear standards for specific medical conditions. The Coast Guard does strive to increase clarity with publication of the Medical Manual, however, the Coast Guard disagrees that improved clarity requires publication of an implementation plan. Discussion of the Coast Guard's internal implementation plans are beyond the scope of the Medical Manual. Moreover, the majority of the policy contained in the mariner medical manual is not new guidance. It is the same guidance, explained in greater detail, that was already implemented in the years following the publication of NVIC 04-08. The Coast Guard also disagrees with the assertion that the Medical Manual should establish condition-specific medical standards. The medical and physical standards for merchant mariner medical certification have already been established in 46 CFR part 10, subpart C. Establishing new medical standards is beyond the scope of a policy document.

Ease of Use and Clarity:

A letter from another commenter requested that the Coast Guard add an appendix that puts common conditions in a table format for quick reference, similar to that used in the International Maritime Organization's (IMO) Guidelines on the Medical Examination of Seafarers. The Coast Guard disagrees on the basis that a quick reference table would not adequately capture the discussion, explanation and rationale that mariners, treating providers and medical examiners need to understand in order to provide quality examinations to the Coast Guard.

#### Requirements for Medical Certification:

Three comment letters recommended that the Medical Manual provide additional medical requirements for medical certification. One letter commented that the Medical Manual should require all mariners to meet the same medical standard, and should provide “specific acceptable parameters” for many conditions to include BMI, pulmonary function, glucose levels, blood pressure, and cardiac function. Another comment letter suggested that the Coast Guard should implement a random medical testing program, similar to that used for drug testing. The third comment letter stated that the physical ability requirements should also include criteria for the speed and facility with which a mariner performs required tasks. The Coast Guard disagrees with these comments. While some of the recommendations pertaining to medical standards may warrant future discussion, changes or additions to the medical and physical requirements for medical certification are beyond the scope of this document. As discussed earlier, the medical and physical standards for medical certification are provided in 46 CFR part 10, subpart C, and changes to those requirements would require a rulemaking.

#### Guidance on the Conduct of the General Medical Examination:

One comment letter addressed the guidance pertaining to the general medical examination and recommended that the mariner medical examination include an evaluation of the mariner’s oral/dental health condition to ensure that there are no untreated infections or other dental problems that could cause significant impairment while at sea. The Coast Guard agrees that such guidance may prove helpful and will work

with MEDMAC to consider whether and what type of guidance would be appropriate for inclusion in a future version of the Medical Manual.

#### Frequency of Required Medical Examinations:

Four comments letters addressed the frequency of required medical examinations. Three commenters opined that it is excessive to require mariners to undergo a medical examination every two years. They recommended that the medical examination for all mariners, including those sailing under the authority of their Standards of Training, Certification, and Watchkeeping (STCW) endorsement, should remain valid for a period of 5 years, unless the mariner's medical condition warrants issuance of a shorter-duration medical certificate. A different commenter requested clarity on how often a mariner is required to obtain a medical exam, noting that in some instances maritime employers require an annual medical examination, even when the Coast Guard does not.

The Merchant Mariner Medical Manual provides detailed discussion of medical examination and medical certification requirements for specific endorsements, and cites the corresponding regulatory references. It is important to note that the medical certificate validity period and the frequency of required medical examinations may differ between endorsements because of the differing legal requirements. Since these requirements are established in regulation, changing them would require a rulemaking and is beyond the scope of this policy document. The medical examination requirements of individual employers are also outside the scope of this policy document.

#### Medical Exam Forms:



One comment letter requested that the Medical Manual provide a list of medical examination forms that would be acceptable in place of the Form CG-719K or KE. The Coast Guard disagrees and did not provide a list of alternative forms because 46 CFR 10.302(a) requires the following: “to qualify for a medical certificate, a mariner must provide evidence of meeting the medical and physical standards ...on a CG-719-K or CG-719-K/E, as appropriate.”

#### Medical Examiners:

Ten comment letters provided comments on the topic of medical examiners. Three commenters requested additional information on the Designated Medical Examiner (DME) program, with one requesting that the Coast Guard publish its timeline and intent to create the DME program. The Coast Guard understands that there is significant interest in the DME program and will publish additional information, as and when appropriate.

Five commenters recommended changes to the regulations regarding individuals who may perform examinations for purposes of the mariner medical certification examination. The Coast Guard considered each of these recommendations, but noted that changes to the regulations are beyond the scope of this policy document.

#### Internal National Maritime Center Processes:

Two comment letters requested that the Manual provide more detail on internal National Maritime Center (NMC) processes. One of these comments expressed concern that the Manual’s instructions would allow non-medical personnel to make medical determinations for U.S. mariners.” This commenter recommended that the Coast Guard

add language to specify that all medical certification decisions will be supervised by a licensed medical officer. The second comment noted that the Manual does not contain “any reassurance or check and balance of examiners, examination quality, or the NMC medical certification process.” This commenter requested that the Coast Guard add language to address these concerns. The Coast Guard considered both of the comments, but does not concur with them. The staffing and internal quality assurance practices of the NMC are beyond the scope of this document. Nonetheless, the Coast Guard affirms that the activities of the NMC Medical Evaluations Division, particularly those related to medical certification, are supervised by a licensed medical officer. On the issue of providing quality assurance for medical examiners, it is important to recognize that medical examiners are not regulated by the Coast Guard. Therefore, providing reassurance or checks and balances of examiners and their exam quality, is inappropriate and is beyond the scope of this document.

#### Positive Drug Tests:

Two comment letters complained that the Manual does not provide guidance for the evaluation of mariners who test positive for illegal drug use. One also requested that the Coast Guard add language to the Medical Manual requiring medical treatment for any mariner who fails a USCG required drug test. The Coast Guard does not concur with these commenters. The Medical Manual does not address requirements related to positive drug tests because the regulations and guidance on the management and disposition of individuals who have a positive drug test are contained in 46 CFR parts 5, 10, and 16. Changes to the DOT and Coast Guard drug testing regulation and policy are beyond the

scope of this policy document. The Medical Manual contains guidance on how the Coast Guard will conduct the medical certification evaluation for individuals who have been diagnosed with a substance abuse disorder. The Medical Manual does not, however, direct treatment nor provide diagnostic instruction, because such areas are beyond the scope this policy document.

#### Reporting Material Changes in Medical Condition for Mariners:

One commenter asked whether a mariner who holds a medical waiver is required to report a material change in their medical condition. The Coast Guard notes that the answer to this question will depend on the provisions outlined in the mariner's medical waiver letter. Some waiver letters require that the mariner report changes in medical condition to the Coast Guard within a specified period of time. If no such provision is provided in the mariner's waiver letter, then the mariner is not required to disclose the change in medical condition until the time of the next medical certificate application.

Three commenters asked whether employers have an obligation to report to the Coast Guard information regarding a change in condition. One of these same commenters also asked how employees could protect themselves from inaccurate reports. The Coast Guard considered each of these comments and advises that this manual does not impose any new reporting requirements on anyone. In response to the concerns about how mariners will be able to protect themselves from inaccurate reports, the Coast Guard offers that the Merchant Mariner Medical Manual only proposes to take action on medical information that the Coast Guard has determined as credible. The information that the Coast Guard would deem credible differs depending upon the circumstances, but

generally will include medical provider documentation, formal incident reports, emergency medical services reports, and investigative reports. The Coast Guard also asserts that mariners will be able to protect themselves from inaccurate reports because this manual provides a standard process for evaluating these reports and further provides mariners with notice of, and the opportunity to respond to, information that indicates that they are no longer fit for medical certification.

#### Medications:

Two comment letters noticed discrepancies in the language in Chapter 7 related to required disclosures of over-the-counter (OTC) medications. One of the commenters also observed that the guidance in the Manual highlighted an error on the most recent version of the Application for Medical Certificate (Form CG-719K, Rev 04/17, Exp. Date 03/31/2021) which incorrectly states that applicants must disclose all OTC medications taken within 30 days prior to the date the applicant signs the CG-719K. Both commenters noted that prior versions of the CG-719K and the Medical Manual only instructed mariners to disclose OTC medications if the medications were used for a period of 30 days or more within the 90 days prior to the date the applicant signs the application to the Coast Guard. They requested that the Coast Guard provide additional language in the Medical Manual to clarify that applicants need only disclose OTC medications, when such medications were used for a period of 30 days or more within the 90 days prior to the date the applicant signs the application to the Coast Guard. The Coast Guard agrees that the language change regarding OTC medication disclosures on the most recent version of the CG-719K was an inadvertent change, and language was added to Chapter 7

of the Medical Manual to clarify the reporting requirements for OTC medications. The Coast Guard will be pursuing a change to CG-719K in the future to correct this change.

Attendant with the language change regarding OTC medications, the Coast Guard also considered the NTSB's comments about impairing medication effects that have contributed to the probable cause of accidents across all modes of transportation. In light of these concerns, the Coast Guard determined that it would be prudent to add additional guidance regarding OTC medications to the Important Safety Warnings paragraph of Chapter 7. Specifically, the additional guidance warns that some OTC medications and preparations may contain intoxicants or other dangerous drugs prohibited by Department of Transportation regulations.

#### NMC Medical Evaluation Procedures for Mariners with Existing Waivers:

One commenter expressed confusion over the discussion of the term *clear error* in Paragraph I.3. of Chapter 3 of the Medical Manual. Paragraph I discusses NMC medical evaluation procedures for mariners with existing waivers, and Paragraph I.3. states that the Coast Guard is not bound to honor a medical waiver that was issued in *clear error*, contrary to duly promulgated policy in effect at time of issuance. The commenter mistakenly interpreted the *clear error* discussion to mean that the Coast Guard would not take responsibility for any erroneous certification decisions that might lead to mishaps or untoward medical situations at sea. In order to clear up this area of confusion, the Coast Guard added language to Paragraph I.3. of Chapter 3, to clarify that the discussion of clear error pertains to medical waivers that were issued in error.

#### Alternative Testing Methodologies for Color Vision:

One comment letter asserted that the discussion of alternative testing methodologies for demonstrating satisfactory color vision contained Paragraph A.1.d.(2)(c) contains an error because it indicates that the Farnsworth D-15 may be used as a potential alternative color vision test for Deck personnel. The Coast Guard disagrees. Title 46 CFR 10.305(a) provides that mariners must demonstrate satisfactory color sense through one of the tests listed in the regulation, or through an alternative test acceptable to the Coast Guard. Paragraph A.1.d.(2) of the Medical Manual provides guidance for mariner applicants seeking to demonstrate satisfactory color vision sense through use of an alternative test, and describes the type of information that the Coast Guard will consider in determining whether an alternative test is sufficient for issuance of the medical certificate. The guidance does not guarantee that any singular test will be accepted as an alternative methodology for any particular mariner applicant, but rather states that the Coast Guard retains final authority for determining whether the testing is acceptable, and recommends that any alternative test be accompanied by a formal color vision evaluation from an ophthalmologist or optometrist.

#### Coast Guard Mission and Motives with Respect to Medical Credentialing:

One commenter asserted that the Coast Guard should “consider its mission and motives with respect to medical credentialing,” and expressed displeasure that the Medical Manual focuses on “medical credentialing without making any decisions on mariner fitness for duty.” The Coast Guard considered this commenter’s concerns and noted that the Medical Manual’s purpose, as stated in Paragraph 1 of the Letter of

Promulgation for the Merchant Mariner Medical Manual, is to “provide guidance for evaluating the physical and medical condition of applicants for merchant mariner medical certificates.” The Coast Guard also notes that making a determination of fitness for certification is distinctly different from making a determination of fitness for duty, and refers the reader to the discussion that follows.

Fitness-for-certification. The medical and physical standards for merchant mariner medical certification are contained in 46 CFR part 10, subpart C. The Coast Guard mariner medical evaluation and certification process seeks to determine whether an applicant meets the medical and physical standards for merchant mariners based upon the information available to the Coast Guard at the time of the certification decision. In accordance with 46 CFR 10.301, the Coast Guard will issue a medical certificate to a mariner meeting the medical and physical standards for merchant mariners. This decision is necessarily a snapshot of the mariner’s medical and physical condition at a single point in time.

Fitness-for-duty. In general, fitness for duty refers to an employee’s ability to perform his/her essential job functions, as specified by the employer, without impairment from medical conditions or medications. There are some important considerations with respect to fitness for duty. First, an individual’s fitness-for-duty status is not static, thus it should be considered whenever an individual reports for duty. Fitness-for-duty status can change suddenly due to an acute illness, injury or incident. As an example, an individual with no medical problems who has been issued a medical certificate and who normally performs their essential job functions without impairment, could become “not-fit-for duty” because of an impairing illness such as the flu, and/or due to impairing medications

used to treat an acute illness. The second important consideration is that a “fitness-for duty” determination refers to an evaluation ordered by an employer to assess an employee’s ability to perform the essential functions of their assigned job (as specified by the employer). Such an evaluation might be requested when the employer has a reasonable belief that an employee will not be able to perform essential job functions because of their medical condition. A variety of state and Federal laws govern fitness for duty determinations depending upon the specific circumstances. Generally, a fitness for duty physical must be job-related and consistent with business necessity. One other important consideration is that the merchant mariner medical qualification standards in part 10, subpart C, are the minimum acceptable standards. Some maritime employers may choose to establish medical and/or physical ability requirements for their employees that are more stringent than the Coast Guard medical certification standards based on factors such as specific duty requirements, austere work environments, and operational tempo. In these cases, the employer’s fitness-for-duty determinations may differ from the medical certification determination because they are based upon different standards. The Merchant Mariner Medical Manual does not preclude marine employers from establishing more rigorous medical or physical ability guidelines; however, there are additional laws and regulations that apply.

#### Line-by-Line List of Changes:

Two commenters requested a detailed, line-by-line list of proposed changes that compares the current language in NVIC 04-08 with each change, addition and deletion made in the Medical Manual. The Coast Guard considered this comment, but determined



that a line-by-line list of changes would not be helpful because of the extensive changes in wording, format and organization between the two documents. Instead, the Coast Guard has already provided a fairly comprehensive discussion of the major changes in Paragraph 6 of the Letter of Promulgation for the Medical Manual.

Medical Certificate Cancellation:

Commenters were both supportive of, and objected to, the proposed medical certificate cancellation policy. After considering the comments, we decided to proceed with the proposed policy. One commenter who opposed the policy nevertheless provided a number of suggested edits to the text which were adopted. Those opposed to the cancellation policy suggested the Suspension and Revocation (S&R) process (46 CFR part 5) as an alternative. The Suspension and Revocation (S&R) process has limited jurisdiction over mariner medical issues. On this subject, S&R is authorized in circumstances where a credentialed mariner has committed an act of incompetence relating to the operation of a vessel (see 46 U.S.C. 7703(4)). A mariner having a disqualifying medical condition is not something addressed through S&R unless and until it has impacted vessel operation. Accordingly, the medical certificate cancellation and waiver processes set forth in the manual effectively address mariner medical qualification and fitness for duty concerns in ways that the S&R system cannot. There are also situations such as mariners using dangerous drugs or operating vessels under the influence of alcohol or other intoxicants that present both medical qualification and S&R concerns, so it may be appropriate for the Coast Guard to utilize both the procedures set

forth in this manual and the S&R process to address and resolve these issues in the interest of safety.

#### Waivers, Limitations, Restrictions:

One commenter requested more detail on limitations and restrictions. The commenter noted that waivers seem not to have been consistently applied to conditions. The Coast Guard agrees in part and over the last few years has provided further guidance on waivers for the most frequently occurring conditions. Those changes to NVIC 04-08 have been carried forward into this manual.

#### Process for Removing Waivers, Limitations and Restrictions:

One commenter complained that the process for removing restrictions and waivers “seems uncomfortably weighted toward taking away one’s ability to sail, without considering that many conditions – even very serious ones – are temporary in nature.” The Coast Guard disagrees and notes that the Medical Manual provides specific guidance on medical evaluation procedures for mariners with short-term conditions (see paragraph J. of Chapter 3 of the Medical Manual). These provisions were included to reduce the burden of imposing and then removing waivers and restrictions for conditions that are expected to resolve in the short-term.

This document is issued under the authority of 5 U.S.C. 552(a), 46 U.S.C. 7101,  
and 46 U.S.C. 7302.

Dated: September 3, 2019.

J. G. Lantz,  
Director, Commercial Regulations and Standards,  
U.S. Coast Guard.

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